



# EC-CERTIFICATE

(Production quality assurance)



This is to certify that the company



## HEINE Optotechnik GmbH & Co. KG

Kientalstraße 7  
82211 Herrsching  
Germany

has implemented and maintains a quality assurance system which applies to the manufacture and final controls of the products.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

### Annex V of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Sphygmomanometers and Accessories (Class Im)

The manufacturer is subject to surveillance according to Annex V, Section 4. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	325735 MR5
Certificate unique ID	170663917
Effective date	2017-02-02
Expiry date	2022-02-01
Frankfurt am Main	2017-01-26

### DQS Medizinprodukte GmbH

Sigrid Uhlemann  
Managing Director

Dr. Thomas Feldmann  
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,  
Tel. +49 (0) 69 95427-300, [medical.devices@dqs-med.de](mailto:medical.devices@dqs-med.de)

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.